APR 21 2008

K080338

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Research & Development Impression
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07 January 2008

510 (k) Summary of Safety and Effectiveness of Hardener Universal Plus (Liquid and Paste) (Project No.: D890/3)

1. Description and Intended Use of the Medical Device:

Hardener Universal Plus (Liquid and Paste) (identical with Activator Universal Plus, Liquid and Paste) is the catalyst of the two component condensation curing silicone dental impression material Cuttersil (hardener and base paste). Base paste and hardener are mixed before use according to the instruction of use.

There is no change in the intended use of the Cuttersil Impression Material because Hardener Universal Plus is a substitute for CutterSil Universal Hardener and the base material remains unchanged. The new D 890/3 hardener has some advantages by comparison with the Cuttersil Hardener Universal:

- The odour of the new hardener is less intensive compared with the old hardener.
- The new D 890/3 hardener shows quite similar physical and handling properties in comparison to the old hardener. The new product also fulfils the requirements of EN ISO 4823.

2. Indication List:

There is no change in the indications when using the new D 890/3 Hardener Universal Plus instead of the "old" Cuttersil Hardener Universal.

3. **Toxicological Evaluation:**

In accordance with the Medical Device Directive 93/42/EWG and national European medical device legislation a medical device is required to be evaluated by the legal medical device manufacturer regarding its clinical performance and safety. This includes an evaluation of biocompatibility in accordance with EN ISO 10993-1.

The biocompatibility of the new D 890/3 Hardener Universal Plus prototype was verified in combination with base paste in accordance with the international standard. The biocompatibility of D 890/3 Hardener Universal Plus in combination with base paste was documented in a Biological Evaluation Report. The benefit overweights the possible risks with the use of the new hardener.

In addition toxicological expert opinions are carried out to assess possible risks by using D 890/3 as hardener in condensation curing dental silicone impression materials and to evaluate recommendations for appropriate warnings. These risk assessments and recommendations have been taken into account in the instruction for use and in the clinical evaluation

4. **Physical Properties and Compliance with International Standard EN ISO 4823:**

There are only minor changes of physical properties by using the new D 890/3 activator Hardener Universal Plus instead of the "old" Cuttersil Hardener Universal which do not affect the effectiveness of the medical device adversely. The physical data for the new D 890/3 hardener are in accordance with the functional specification for D 890/3 and the requirements of EN ISO 4823.

Based on the test data the new hardener it can be concluded is effective for taking of detailed dental impressions.

5. **Clinical Evaluation:**

D 890/3 Hardener Universal Plus is a hardener for condensation curing dental impression material which is in general classified as a class I medical device under the Medical Device Directive 93/42/EEC.

Considering the evaluated data, clinical evaluation and technical results for D 890/3 hardener it is concluded that the product can be expected to exhibit the claimed technical performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighted against their benefits in dentistry. Therefore the expert stated for hardener D 890/3 that the benefits overweight the possible risks if the product is applied according to the instruction for use.

6. Summarized Evaluation:

D 890/3 Cuttersil Hardener Universal Plus is a substitute for Cuttersil Hardener Universal. The type of setting reaction is well known and does not change.

The physical properties meet the requirements of the functional specification and EN ISO 4823. The biocompatibility of the new hardener was tested according to the requirements of EN ISO 10993 and additional toxicological expert opinions have been carried out. The Biological Evaluation Report showed the benefit overweights the possible risks with the use of the new hardener.

Based on the results of the clinical evaluation it is concluded that the product can be expected to exhibit the claimed performance and that potential undesirable clinical effects and risks seem well controlled and acceptable when weighed against their benefit in dentistry.

The risk analysis according to EN ISO 14971 was carried out for the new D 890/3 hardener and showed that the application of D 890/3 according to the manufacturer's instruction for use shows an acceptable risk.

The new D 890/3 hardener meets all relevant requirements for condensation curing dental silicone impression materials in accordance with the Medical Device Directive 93/43/EWG and national European medical device legislation. Based on the actual facts D 890/3 Cuttersil Hardener Universal Plus is considered to be effective and safe when using it in accordance with the manufacturer's information for use.

Dr. Martin Grunwald Date: Signature:

Annegrete Wegner Date: Signature:

Release:

Dr. Barbara Bräu Date: Signature

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2008

Heraeus Kulzer GmbH
C/O Ms. Cheryl Zimmerman
Director, Quality Assurance & Regulatory Affairs
Heraeus Kulzer, Incorporated
4315 South Lafayette Boulevard
South Bend, Indiana 46614

Re: K080338
Trade/Device Name: CutterSil Hardener Universal Plus
Regulation Number: 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: February 4, 2008
Received: February 11, 2008

Dear Ms. Zimmerman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if Known): K080338

Device Name: *CutterSil Hardener Universal Plus*

Indications For Use:

CutterSil Activator Universal Plus paste and liquid are used as a catalyst to induce polymerization of the CutterSil base paste which is used for all inlay, crown and bridge, partial and edentulous impressions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ ____ ____

Concurrence of CDRH, Office of Device evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080338

(Optional Format 1-2-96)